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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,444	12/21/2001	Kang P. Lee	ASPEN 112 US	1737

7590 11/18/2002

Bruce F. Jacobs
P.O. Box 390438
Cambridge, MA 02139

EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,444	LEE ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (6,403,056 B1).

Unger teaches method for delivering bioactive agents to a patient and/or treating conditions in a patient comprising administering to the patient a composition comprising a charged lipid, a counter ion, a lipid covalently bonded to a polymer and a bioactive agent (col. 2, lines 25-35).

Unger discloses that "aerogel" refers to generally spherical or spheroidal entities which are characterized by a plurality of small internal voids. The aerogels may be

formulated from synthetic materials and/or natural materials, such as carbohydrates or proteins (col. 4, lines 66 to col. 5, line 4).

Unger also discloses that bioactive agents and therapeutic agents can be used in the preparation for treatment or diagnostic purposes. The said agents are selected from proteins and peptides, such as insulin (col. 6 and col. 42, lines 45-67) and non-protein agents such as antibiotics, steroids, antitumor agents, etc (col. 43, lines 10-37).

Unger discloses physical characteristics of gaseous precursors and diameter of emulsified droplet to form a 10 μm vesicle (table 1).

Although Unger reference does not specifically state that aerogel particles are soluble in human pulmonary surfactant, it does discloses that aerogel particles are synthesized from carbohydrates, therefore the solubility is an inherent property of the carbohydrate particles. Also Unger does not specifically teach the formulations for pulmonary delivery, however "for pulmonary delivery" is an intended use recitation and does not support patentability. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the teachings of Unger by forming the particles for pulmonary delivery because of the benefits of administration of therapeutic agents through inhalation and its ease of use for patients compared to injections, oral and other routes of delivery.

Claims 2-4 and 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (6,403,056 B1) as applied to claims 1 and 5-7 above, and further in view of Abbott et al (6,277,489).

Unger, discussed above, lacks specific teachings on steps of preparation of aerogel particles.

Abbott teaches that solution-phase methods can be used to coat micrometer-sized, silica particles with polycrystalline metal films. The particles can also be incorporated into an aerogel (col. 3, line 65 to col. 4, line 21). Abbott also teaches that the preferred embodiment, the recognition moiety, is a drug moiety. Classes of useful agents include non-steroidal anti-inflammatory drugs, codein, tranqulizer and sedative drugs, etc (col. 17).

Abbott discloses that the materials of the invention can also be formed into aerogels. Aerogels are useful in catalysis and detection and have interesting thermal and optical properties. Aerogels are characterized by accessible, cylindrical, branched mesopores. Owing to their high porosity and low density aerogels are unique materials. Aerogels are generally formed by the controlled condensation of small particles. Appropriate methods for producing aerogela include, supercritical drying of liquid from a wet gel comprising the particulate material. A solvent containing the particulate material is put into its supercritical state. The wet gel is placed in an autoclave and covered with additional solvent (col. 39, lines 6-35).

Abbott discloses chemical parameters of the gel particles in column 55 lines 26-31 and column 56, lines 20-51. The silica gels have 50-200 mesh, particles sizes range from 50 to 200 μm, surface area of 300 –500 m^2/g, pore volume 0.75 cm^3/g and 1.2 cm^3/g, and pore diameters between 60 and 150 A°.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the teachings of Unger on the preparation containing active agent and an aerogel particle by adding the method of producing the aerogel particles and other active agents suitable for combination with the aerogel particles, as taught by Abbott because of the disclosed benefits of aerogels in delivering a bioactive to the patients and the method of producing the aerogel particles and their properties are important in the production of the formulation.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure, Platz et al (6,123,936).

Platz teaches methods and compositions for spray-dried, dry powder compositions, particularly interferon-beta, for treating conditions in humans that are responsive to treatment with interferons. Platz describes the term "powder" to mean a composition that consists of finely dispersed solid particles that are free flowing and capable of being readily dispersed in an inhalation device and subsequently inhaled by a subject so that the particles reach the lungs to permit penetration into alveoli (col. 3, lines 4-14).

Platz discloses that the dry powder compositions are readily absorbed in the lungs without the need to employ penetration enhancers. The types of pharmaceutical excipients that are useful as carriers include stabilizers such as human serum albumin (HAS), bulking agents such carbohydrates, amino acids and polypeptides etc (col.4, lines 7-30).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
November 14, 2002

MICHAEL G. HARTLEY
PRIMARY EXAMINER